UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/590,889	06/04/2007	Peter Svete	33668US-PCT	3731
	7590 03/16/201 - LUEDEKA, NEELY	EXAMINER		
P.O. BOX 1871		RAO, SAVITHA M		
Knoxville, TN	57901		ART UNIT	PAPER NUMBER
		1614		
			MAIL DATE	DELIVERY MODE
			03/16/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)				
000 4 11 0	10/590,889	SVETE ET AL.				
Office Action Summary	Examiner	Art Unit				
	SAVITHA RAO	1614				
The MAILING DATE of this communication app Period for Reply	pears on the cover sheet with the c	orrespondence address				
A SHORTENED STATUTORY PERIOD FOR REPL'WHICHEVER IS LONGER, FROM THE MAILING D.  - Extensions of time may be available under the provisions of 37 CFR 1.1 after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period of Failure to reply within the set or extended period for reply will, by statute Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be timwill apply and will expire SIX (6) MONTHS from a cause the application to become ABANDONE	N. nely filed the mailing date of this communication. D (35 U.S.C. § 133).				
Status						
1) ☐ Responsive to communication(s) filed on <u>22 D</u> 2a) ☐ This action is <b>FINAL</b> . 2b) ☐ This     3) ☐ Since this application is in condition for allowal closed in accordance with the practice under E	action is non-final.  nce except for formal matters, pro					
Disposition of Claims						
<ul> <li>4) ☐ Claim(s) 1,3,4,6-10 and 18 is/are pending in the application.</li> <li>4a) Of the above claim(s) is/are withdrawn from consideration.</li> <li>5) ☐ Claim(s) is/are allowed.</li> <li>6) ☐ Claim(s) 1,3-4, 6-10 and 18 is/are rejected.</li> <li>7) ☐ Claim(s) is/are objected to.</li> <li>8) ☐ Claim(s) are subject to restriction and/or election requirement.</li> </ul>						
Application Papers						
9) The specification is objected to by the Examine 10) The drawing(s) filed on is/are: a) acc Applicant may not request that any objection to the Replacement drawing sheet(s) including the correct 11) The oath or declaration is objected to by the Examine 11.	epted or b) $\square$ objected to by the Eddrawing(s) be held in abeyance. Seetion is required if the drawing(s) is obj	e 37 CFR 1.85(a). lected to. See 37 CFR 1.121(d).				
Priority under 35 U.S.C. § 119						
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No.</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>						
Attachment(s)		(PTO 440)				
<ol> <li>Notice of References Cited (PTO-892)</li> <li>Notice of Draftsperson's Patent Drawing Review (PTO-948)</li> <li>Information Disclosure Statement(s) (PTO/SB/08)</li> <li>Paper No(s)/Mail Date</li> </ol>	4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal P 6) Other:	ate				

#### **DETAILED ACTION**

Claims 1, 3-4, 6-10 and 18 are pending. Receipt and consideration of Applicants' amended claim set and remarks/arguments filed on 12/22/2010 is acknowledged.

Claims 1, and 18 are amended and claim 2,5 and 19 are cancelled. Claims under consideration in the instant action are claims 1, 3-4, 6-10 and 18.

Applicants' arguments, filed 12/22/2010 have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

### Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

- 2. Ascertaining the differences between the prior art and the claims at issue.
- 3. Resolving the level of ordinary skill in the pertinent art.
- 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

It is noted that the Antoncic et al.(US 7271269) used in the 103(a) rejections set forth in office actions dated 03/10/2008 and 09/30/2008 was disqualified as a prior art reference for purposes of any alleged "obviousness" rejection by operation of 35 U.S.C 103 (c) by the applicants. That reference is withdrawn from use in the 103 (a) rejection.

The instant rejection set forth below uses the WIPO document of Antoncic. (WO 2004/066997) in the following rejection and it is noted that this reference (WO 2004/066997) additionally qualifies as prior art under another subsection of 35 U.S.C. 102 (a), and therefore, cannot be disqualified as prior art under 35 U.S.C. 103(c).

Rejection of claims 1, 3-4, 6-10 and 18 under 35 U.S.C. 103(a) as being unpatentable over to Antoncic et al. (WO 2004/066997) in view of WHO drug

Art Unit: 1614

information(WHO drug information Vol.16, (4), 2002, pages 1-12) as evidenced by Maggi et al. (European Journal of pharmaceutics and Biopharmaceutics, 48, 1999, pages 37-42) further in view of Bharatarajan et.al. (US 2006/0177498) is maintained for reasons of record restated below.

Amended claims 1 and 18 include the limitation potassium salt of losartan" which was the limitation in the now cancelled claims 2 and 19. Claims 2 and 19 were appropriately rejected in the rejection below in the non-final action dated 06/22/2010 and as such amended claims 1 and 18 are appropriately rejected by the rejection below.

Antoncic et al. discloses crystalline and amorphous potassium salts of Losartan and pharmaceutical compositions comprising them (abstract). Antoncic. discloses that it is known that Losartan potassium exists in at least two polymorph forms Form I and Form 2 (page 4, 2<sup>nd</sup> paragraph) and further discloses other references which teaches Losartan form III, Form IV and Form V (page 5, 2<sup>nd</sup> paragraph) (reads on instant claims 1 and 2). Antoncic et al. discloses a potassium salt of losartan characterized by a powder X-ray diffraction pattern with peaks at about 20 6.9, 13.8, 20.6, 24.8, 28.7, 29.2° (Form X) (page 24, 3<sup>rd</sup> paragraph) and pharmaceutical composition containing polymorphic forms of losartan specifically the form exhibiting strongest diffractions at around 20 6.9, 13.8, 20.6, 24.8, 28.7, 29.2° (Form X) (page 29, 1st and 2nd paragraph) (reads on instant claims 4). Antoncic et al. discloses an aspect of their invention where in the pharmaceutical active ingredient of the composition is the amorphous form of losartan (page 31, 3rd paragraph) or a crystalline form of Losartan (page 31, last paragraph) and film coated tablet formulations of potassium salt of Losartan wherein

Page 5

Art Unit: 1614

tablet cores with a mass of 160 mg comprising excipients such as lactose, microcrystalline cellulose, starch and aerosil was prepared and coated (page 29, 3<sup>rd</sup> paragraph and page 30, 5<sup>th</sup> paragraph) *(reads on the composition comprising a tablet core wherein the tablet core comprises an active pharmaceutical" limitation of instant claim 1 and instant claim 5)*. The examples 50, 52a and 52b disclosed by Antoncic. describe the coated tablet formulations of polymorphic forms of potassium salt of Losartan (pages 66-70). Antoncic et al teaches the inclusion of silicified microcrystalline cellulose in the tablet core at 40% of the total weight of the composition and film coating comprising ethyl cellulose in the concentration of 1.95% or stearic acid at 0.6% weight of the composition (see below) (examples 52a and 52b) .The following table lists the taught excipients along with the %weight in each formulation,

Art Unit: 1614

Antoncic et al. Example 52a	Weight, mg	Component weight %/	] .
		finished dosage form	'
Losartan potassium (core)	100 mg	29.74	n
Silicified Microcrystalline	199.2 mg	40.0	Antonci
Cellulose (core)			c et al.'s
Silica colloidalis anhydrica	3.2 mg	0.95%	exampl
(core)			e 52a
Ethylcellulose (coat)	6.54 mg	1.95%	above
Finished dosage weight total	336.22		calculati
(plus 0.22 mg of talc)			on of %
Antoncic et al. example 52b			weight
Losartan potassium (core)	100.00 mg	29.74	of colloidal
Silicified Microcrystalline	19932 mg	40	anhydro
Cellulose (core)			us silica
Silica Colloidalis Anhydrica	1.6 mg		with
(core)			referenc
Stearic acid (coat)	2.1 mg	0.6	e to the
Finished dosage weight total	336.22	0.5	finished
(plus 0.22 mg of talc)			dosage

weight as shown in the above table yields 0.95%. Antoncic et al. discloses that Losartan is used as an effective drug for the treatment of hypertension (Page 1, last

Art Unit: 1614

paragraph, page 32, 2<sup>nd</sup> paragraph 1) and additionally, discloses that the pharmaceutical composition of his invention can be in a form suitable for peroral or parental application and is indicated for treating hypertension in addition to teaching that his compositions can be embodied in the form of tablets, capsules etc. (Page 29, 2<sup>nd</sup> paragraph) (Reads on instant claims 18-19).

With respect to the limitation in instant claim 1 wherein "the pharmaceutical ingredient which exists in a first polymorph form susceptible to interconversion into one or more other polymorph forms" Antoncic. teaches the potassium salt of Losartan with the X-ray diffraction pattern as instantly claimed. As such the pharmaceutical ingredient taught by Antoncic. is the same as that instantly claimed. The compounds and its characteristics of properties cannot be separated. . Since the reference teaches the instantly claimed pharmaceutical composition comprising the instantly claimed compound which is the "potassium salt of Losartan", which possess the instantly claimed crystal structure with identical X-ray diffraction patterns as taught by applicant it necessarily follows that it the compound will possess these properties which is the ability to exist in the first polymorph form susceptible to interconversion into one or more other polymorph forms" alleged by Applicant, absent factual evidence to the contrary. "Products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Office lacks laboratory facilities to test the prior art

Art Unit: 1614

compounds and compositions. It is incumbent upon applicants to provide data demonstrating that the properties of the disclosed prior art compounds/compositions are different from the claimed compositions.

Antoncic et al. do not teach the exact concentration of the stabilizer instantly claimed which is between 1-10% by weight of the composition and does not teach the specific anhydrous silicon dioxide of the Syloid form instantly claimed.

However, WHO drug information document teaches Silicas (silicon dioxide) as being widely used in the manufacture of pharmaceuticals, cosmetics and food products where they are used as an adsorbent, anticaking agent, glident, suspending agent, tablet disintegrant and viscosity-increasing agent and teaches "colloidal Anhydrous silica (BP) and colloidal silicon dioxide (USPNF) and silica colloidalis anhydrica (PhEur) as trivial names and chemical names adopted by different pharmacopeias (page 3 under Silicas and beginning of page 4).

Maggi et al. is used here as evidence to demonstrate that Syloid 244 is nothing but colloidal silicone dioxide used as one of the excipients (page 38, right column, 4th paragraph). As such the prior art provides ample suggestions and teachings to demonstrate that Syloid is the same as the colloidal anhydrous silica used in the formulation of Antoncic. and would therefore possess similar properties.

In addition, Bharatarajan et al. teach the use of Syloid AL-1 claimed in Instant application as one of the suitable excipients with low moisture content that prohibit uptake of moisture and provide the effect of increased stability of formulations with low water contents excipients [0016, 0025-0026]. Bharatarajan et al. teach a tablet

formulation of Ramipril in Example 3, comprising the active ingredient, microcrystalline cellulose at 53.9% by weight of the total composition and precipitated Silicon dioxide (Syloid) at 4.8% by weight of the total composition and further teach that the compositions of example 3 did not show any significant degradation over 4 weeks at accelerated testing conditions [0036-0037].

With reference to the concentration of the stabilizer claimed in the instant claims at 1-10%, Antoncic et al.teaches his composition to comprise 0.95% and Bharatarajan et al. teach their composition to comprise about 4.8% of silicon dioxide which renders the stabilizer weight of 1-10%, claimed in instant claims obvious. In addition, Inclusion of anhydrous silicon dioxide in tablet formulation for stability purposes is taught in the art and as such, it would be within the skill of an ordinary artisan to be able to modify the weight ratio of the excipients in order to obtain the desired stability and bioavailability profile of the active drug. It is also noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

With respect to the inclusion of Syloid silicon dioxide in the formulation as instantly claimed in claims 9-1, The art teaches that Syloid silicon dioxide instantly claimed is the same as colloidal anhydrous silica taught by Antoncic et al. Accordingly, it would have been obvious to an ordinarily skilled artisan to utilize the registered traded mark version of the colloidal silicone dioxide in the formulation as one of the type of colloidal anhydrous silica taught by Antoncic et al. Syloid silicon dioxide is a functional

equivalent of colloidal anhydrous silica used by Antoncic et al. and it is further taught to function well as a stabilizer.

As such an ordinarily skilled artisan would be motivated to utilize Syloid silicone dioxide as a stabilizer in the formulation of Antoncic et al. as an equivalent replacement to the colloidal silica Anhydrica. Substituting equivalents, namely silicon dioxide, motivated by the reasonable expectation that the respective species will behave in a comparable manner or even provide comparable results in related circumstances, see *In re Ruff*, 256 F.2d 590, 118 USPQ 340 (CCPA 1958) is prima facie obvious. Moreover, the express suggestion to substitute one equivalent for another need not be present to render the substitution obvious, see *In re Font* 213 USPQ 532. Due to the fact that Bharatarajan et al. teach and provide the skilled artisan with the necessary motivation to use a Syloid silicon dioxide in a drug compositions such as tablets, and Antoncic et al. et al. teach a formulation of Losartan comprising anhydrous colloidal silicon dioxide, one having ordinary skill in the art is clearly provided with direction and ample motivation to utilize Syloid silicon dioxide in the method of Antoncic et al. and at the concentration used by Bharatarajan et al. as Syloid silicone dioxide and colloidal silica Anhydrica are functional equivalents.

Accordingly, the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains because it would have been *prima facie* obvious to the skilled artisan to substitute known equivalents in a pharmaceutical formulation with a goal of

achieving same or better effect.. Selection of excipients and the amounts to be used can be readily determined by one of ordinary skilled in the arts based upon experience and consideration of standard procedures and reference work in the field.

The experimental data disclosed by the applicant (Specification pages 11-15) to demonstrate the properties of the claimed composition is noted and acknowledged.

Data presented demonstrates the intrinsic stabilizing property of anhydrous finely divided silicon dioxide and cannot be used to overcome the instant rejection.

# Response to applicant's arguments filed on 12/22/2010:

Applicant traverses the above rejection with the following arguments:

- a. Antoncic et al. does not teach the inclusion of Colloidal silicon dioxide, Bharatarajan is not directed to compositions comprising losartan, and the excipients in Bharatarajan are used to prevent reactive degradation of ramipril and Bharatarajan teaches nothing about how one could prevent polymorphic interconversion of pharmaceutical active ingredient that are susceptible to such interconversion such as losartan.
- b. The unique combination of losartan together with anhydrous colloidal silicon dioxide is shown to limit undesired interconversion of losartan to other polymorph forms and nothing in the prior art would have suggested this to a person of ordinary skill.
- c. The teachings of Bharatarajan are unrelated to the issues facing Applicants in the present situation and no reason has been shown as to why a person of ordinary skill would look to Bharatarajan to solve the problem of interconversion of Losartan.

Applicant's traversal arguments for this rejection have been fully considered, but are not found to be persuasive.

First, it should be noted that the above rejection was made under 35 U.S.C. 103(a) and therefore none of the cited references has to teach every limitation of the instant claims. It is noted that rejections under 35 U.S.C. 103(a) are based on combinations of references, where the secondary references are cited to reconcile the deficiencies of the primary reference with the knowledge generally available to one ordinary skill in the art to show that the differences between Applicant's invention and the prior art are such that they would have been modifications that were *prima facie* obvious to the skilled artisan. It is noted that the claimed invention is not required to be expressly suggested in its entirety by any one or all of the references cited under 35 U.S.C. 103(a). Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). Applicant has not overcome the rejection.

In response to applicant's arguments against each reference individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In the instant case, Antoncic et al. explicitly teaches pharmaceutical compositions comprising potassium salts of Losartan, the polymorphic form of which is the same as instantly claimed which includes different excipients such as colloidal silica, silicified microcrystalline cellulose etc. Antoncic et al. teaches his composition to

comprise 0.95% and Bharatarajan et al. teach their composition to comprise about 4.8% of silicon dioxide which renders the stabilizer weight of 1-10%, claimed in instant claims obvious. As such inclusion of anhydrous silicon dioxide in tablet formulation for stability purposes is taught in the art and as such, it would be within the skill of an ordinary artisan to be able to modify the weight ratio of the excipients in order to obtain the desired stability and bioavailability profile of the active drug. It is noted that the excipients cited by the applicants are well known in the pharmaceutical art and offer multiple properties to the final composition which are desired. For e.g. polyethylene glycol would function as a solvent, emollient and a stabilizer. As such inclusion of one or more of these excipients in any pharmaceutical composition is not novel and would be obvious to an ordinarily skilled artisan.

In response to applicant's argument that the references fail to show certain features of applicant's invention, i.e. unique combination of losartan together with anhydrous colloidal silicon dioxide is shown to limit undesired interconversion of losartan to other polymorph forms, it is noted that the features upon which applicant relies (i.e., unique combination of losartan together with anhydrous colloidal silicon dioxide is shown to limit undesired interconversion of losartan to other polymorph forms) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Additionally, it is noted that the combination of losartan together with anhydrous colloidal silicon dioxide is taught in the prior art and there is no indication by Antoncic et al. that the

concentration of 0.95% silicon dioxide renders the composition unstable. Further, addition of colloidal silicon dioxide and optimizing the amount added to any pharmaceutical compositions to increase stability is well within the capabilities of an ordinarily skilled artisan and they would arrive at the instantly claimed concentration upon routine optimization.

Page 14

In response to applicant's argument that The teachings of Bharatarajan are unrelated to the issues facing Applicants in the present situation and no reason has been shown as to why a person of ordinary skill would look to Bharatarajan to solve the problem of interconversion of Losartan, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See Ex parte Obiaya, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). Both Antoncic et el. and Bharatarajan are drawn to the art of pharmaceutical compositions, Bharatarajan discloses Syloid AL-1 claimed in instant application as providing excellent stability to the pharmaceutical composition for over 4 weeks at accelerated testing conditions and teaches Syloid AL-1 as a suitable excipients with low moisture content that prohibit uptake of moister and provide the effect of increased stability of formulations which is ample motivation to an ordinarily skilled artisan to utilize Syloid AL-1 in pharmaceutical compositions and titrate the concentration of Syloid AL-1 around that taught by Bharatarajan. Further, it is noted that Antoncic et al. already teaches the inclusion of colloidal silicon dioxide and since Syloid Al-1 is a registered trade mark version of the

colloidal silicon dioxide, it would have been obvious to utilize Syloid Al-1 instead of colloidal silicon dioxide in the composition of Antoncic.

<u>Finally In response to applicant's argument that there is no suggestion to </u> combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). It is also noted that "The use of patents as references is not limited to what the patentees describe as their own inventions or to the problems with which they are concerned. They are part of the literature of the art, relevant for all they contain." In re Heck, 699 F.2d 1331, 1332-33, 216 USPQ 1038, 1039 (Fed. Cir. 1983) (quoting In re Lemelson, 397 F.2d 1006, 1009, 158 USPQ 275, 277 (CCPA 1968)). A reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill the art, including nonpreferred embodiments. Merck & Co. v. Biocraft Laboratories, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989).

Accordingly, the arguments set forth by the applicant are unpersuasive and the rejection is maintained.

### Conclusion

## Claims 1, 3-4, 6-10 and 18 are rejected. No claims are allowed

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SAVITHA RAO whose telephone number is (571)270-5315. The examiner can normally be reached on Mon-Fri 7.00 am to 4.00 pm..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Application/Control Number: 10/590,889 Page 17

Art Unit: 1614

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/SAVITHA RAO/ Examiner, Art Unit 1614

/Ardin Marschel/ Supervisory Patent Examiner, Art Unit 1614